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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,180	11/14/2001	Jian Chen	D0051 NP	2612
23914	7590	11/03/2004	EXAMINER	
STEPHEN B. DAVIS BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000			MOORE, WILLIAM W	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/993,180	<b>Applicant(s)</b> CHEN ET AL.	
	<b>Examiner</b> William W. Moore	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 53-66 and 76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 53-66 and 76 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Response to Amendment*

Applicant's amendment filed October 18, 2004, has been entered, canceling claims 67 through 75, amending claims 53 and 56, and adding a new claim, claim 76, thus claims 53-66 and 76 now remain in the application.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 53-66 and 76 are for reasons of record rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility.

Applicant's arguments filed October 18, 2004, have been fully considered but they are not persuasive. Applicant asserts that the associations of expression of a claimed polynucleotide with testicular cancer, a "neoplasm", among neoplasms of six other endocrine organs, and among twenty other organs, organ systems, tissues and portions of the human anatomy, that Applicant proposes at page 190 of the specification, as well as among cancers of 32 other organs and 9 autoimmune diseases at page 208 of the specification, constitutes a "specific" utility. It is the specificity of the disclosure of an alleged utility, rather than the substantiality or the credibility or an alleged utility that is at issue. A claimed invention must possess a specific, substantial, and credible *in vitro* or *in vivo* utility, but the paragraphs to which Applicant points at pages 190 and 208 of the specification are not considered to identify any specific utility for the invention known to the inventors at the time the application was filed where the diffuse assertions at these pages indicate the contrary: that Applicant neither knew of nor appreciated a specific utility for a claimed polynucleotide at the time the application was filed that would permit an immediate use by the public of a disclosed polynucleotide or any use by the public of

an expression vector or host cell comprising a disclosed polynucleotide. The litanies of dozens of disease states with which expression of a claimed polynucleotide is alleged are not evidence that the inventors at the time the application was filed contemplated or recognized a particular, specific, utility for a claimed product.

At pages 6-8 of the Response, Applicant refers to a Declaration by a party Feder, that may have been a Declaration under 37 CFR 1.132, that did not accompany the Response but that may provide experimental results of an association of 10-fold greater expression of a claimed polynucleotide in testicular cancer cells over levels of expression in non-cancer cells. Had the Declaration been present for consideration, it is not agreed that it could be dispositive of the issue of a disclosure of a specific utility known to the inventors at the time the application was filed because Applicant's arguments in the Response indicate that experimentation was conducted after the application had been filed, and because the diffuse assertions of utility to which Applicant points, among other equally diffuse assertions elsewhere in the specification, are strong evidence that the inventors neither recognized nor appreciated any utility specific to a claimed polynucleotide at the time the application was filed. Neither does the prior art disclosure of Frazer et al. support Applicant's allegation that a claimed polynucleotide has at least a diagnostic utility, or a utility well-established in the art, in detecting testicular cancer. This is because Frazer et al. establish instead that elevated levels of expression of transcripts encoding the very closely-related serpin "centerin" are instead associated with the differentiation of germinal "B cells" – pro-myelocytes of the peripheral circulation system – and with their malignant counterparts of Burkitt's lymphoma. While the utilities at pages 190 and 208 of the specification are substantial, none are specific to a polynucleotide that encodes the disclosed, native, LSI-01 serpin. A method of use of a material for further research to determine, e.g., its specific

biological role, thus identifying or confirming a "real world" context for its use, cannot be considered to be a "substantial utility". *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). Retrospective demonstration of one among many prospective, potential, utilities cannot rise to the level of a credible assertion of a specific *in vivo* or *in vivo* utility recognized and appreciated by the inventors at the time the application was filed, thus the rejection of record of claims 53-66, as well as the new claim 76 which recites subject matter previously included in claim 53, is maintained.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53-66 and 76 are also rejected for reasons of record under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Applicant separately addresses this rejection at page 12 of the Response filed October 18, 2004, but does not establish that enablement of a specific use of a claimed product is disclosed in the application as of its effective filing date of November 14, 2000.

#### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1652

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now 571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The fax phone numbers for all communications for the organization where this application or proceeding is assigned remains 703.872.9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore  
October 29, 2004



WILLIAM W. MOORE  
Examiner  
Art Unit 1652